
United States Department of Agriculture (USDA)



Grain Inspection,
Packers and Stockyards Administration

GIPSA Quality Standard

A Management Standard for Official Service Providers

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Quality Management System (QMS) Overview

INTRODUCTION

A Quality Management System (QMS) is a management tool that considers all parts of an organization related to quality, including management responsibility, customer focus, resource management, service delivery and the continual improvement of the operation. A QMS can be described as a network of interconnected processes. A process is a series of steps or actions that begin with an input and result in an output. When a group of processes are put together, it becomes a system of processes working together collectively to achieve the common objective of customer satisfaction. In early manufacturing systems, Henry Ford initiated several processes to form an assembly line. By putting those processes together, he was able to efficiently and economically provide customers with affordable and reliable quality automobiles. In a modern QMS, each process within an organization from creating an effective work environment to ensuring the quality of service delivery, are inter-related to ensure consistent delivery of a product or service.

Developing and implementing a QMS helps an organization focus on quality management objectives. For best results when seeking to achieve such objectives, a quality system must be managed according to specific quality management standards. In today's marketplace, a business must document its conformance to these quality standards to ensure that tasks are performed on time and within the structured goals of the organization.

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of its customers. Managing an organization encompasses quality management among other management disciplines.

Eight quality management principles have been identified and internationally accepted as the best means top management can use to lead an organization towards improved performance.

- a) **Customer-Focused:** An organization must take pride in meeting customer requirements. The organization depends on customers so it must understand their requirements and strive to exceed its customer expectations.
- b) **Leadership:** Continual improvement and customer satisfaction are achievable when led by top management. Leaders provide direction and make sure all people are on course.
- c) **Involvement of People:** People, not machines, make quality a reality. When vision, objectives, and plans are shared, everyone will be working together to benefit the organization.
- d) **Process Approach:** Organize work the way it naturally flows. When activities are linked together there is a structure to effectively monitor, measure, and improve each process.

- e) **System Approach:** Grouping processes creates a system. Top management organizes the processes into a system to meet legal and customer requirements.
- f) **Continual Improvement:** To achieve excellence, never settle for status quo; continue to make things better. Make continual improvement of the entire organization a permanent objective.
- g) **Factual Approach to Decision Making:** Make effective decisions based on facts obtained through logical analysis of monitoring and measurement data.
- h) **Mutually Beneficial Supplier Relationship:** Recognize the interdependency between the organization and the suppliers who provide products or services. Work toward a mutually beneficial relationship that will result in a win-win outcome.

These eight quality management principles form the basis for the GIPSA Quality Standards developed by the United States Department of Agriculture (USDA) Grain Inspection, Packers and Stockyards Administration (GIPSA), Federal Grain Inspection Service (FGIS), under which an Official Service Provider (OSP) must operate when providing services on behalf of GIPSA.

BACKGROUND

GIPSA's Federal Grain Inspection Service (FGIS) facilitates the marketing of U.S. grain and related agricultural products by establishing standards for quality assessments, regulating handling practices, and managing a network of Federal, State, and private laboratories known as the official system. The Official System provides impartial, user fee funded official inspection and weighing services under the authority of the United States Grain Standards Act, and the Agricultural Marketing Act of 1946 as amended. FGIS also establishes standard testing methodologies for accurately and consistently measuring the quality of grain and commodity. Similar to the Official standards for grading grain and commodities, the Official GIPSA Quality Standards play an integral part in how services are delivered within the official system. Customers of the official system will experience a higher degree of confidence in the product or service provided when the OSPs in the official system conform to a quality system based on an established management standard. Conformance to the GIPSA Quality Standard will ensure that an OSP can clearly demonstrate the following:

- a) Consistent quality products and services produced through the use of documented procedures
- b) Establishment of management and assessment procedures
- c) Implementation of corrective and preventive actions
- d) Retention of records and data describing the quality of the product or service
- e) Continuous improvements embraced throughout the organization

PURPOSE

This GIPSA Quality Standard was developed based on internationally accepted quality management principles under which an organization should operate. GIPSA adopted these principles as its quality management philosophy because it correlates with the core values and concepts of many quality improvement programs which emphasize:

- a) Understanding and meeting customer needs and requirements
- b) Considering processes in terms of added value
- c) Obtaining best quality results of process performance and effectiveness
- d) Continual improvement of processes

This GIPSA Quality Standard is part of a wider effort to introduce more flexibility, accountability, and innovation into the GIPSA/OSP relationship. The end result will be high performing OSPs that drive progress within the official system. Each OSP must prepare its own unique Quality Management System that fits its organizational culture and meets the requirements set forth in the Quality Standard. In addition to adhering to the Quality Standard, the OSP must meet certain selection criteria and specific requirements.

GLOSSARY OF TERMS

Term	Definition
Audit	Systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. These are performed internally (informal) and externally (formal).
Compliance	The affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant laws, regulations, SOPs, handbooks, and directives. Individuals and companies comply with the regulations.
Conformance	Refers to adherence to quality management standards. If your organization meets these requirements, you can say that it conforms to these requirements.
Corrective Action	This term is used to define the correction of non-conformity or non-compliance. The intent of this term in the Quality Standards is to document the steps that are taken to remove or eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence or to make quality improvements. Corrective actions address actual problems. In general, the corrective action process can be thought of as a documented problem solving process.
Customer	Any entity (organization or person) who receives products or official services from the OSP. For the purposes of the Quality Standards, GIPSA is not considered an OSP customer since the OSP must enter into an agreement with GIPSA.
Document	Refers to information and the paper, sign board, computer monitor, etc., that is used to bring it into existence. A document can be digital or physical. There are many types of documents, for example specifications, quality manuals, quality plans, records, and procedure documents. A document is considered living because it changes over time.
Documentation	All of the information generated by the OSP to conform to the Quality Standards. This includes documents, records, handbooks, SOPs, and any other materials.
Documented Procedures	A document that describes an activity indicating who is responsible for the activity, where the activity occurred, and the frequency; a document that provides information to carry out a process or activity in an orderly manner. The QMS requires 8 documented procedures.
Official Service Provider (OSP)	An organization granted the authority to perform work on behalf of GIPSA through designations, delegations, cooperative agreements, and contracts.
Outreach Methods	Proactive efforts undertaken by the OSP to build and foster new and existing customer relationships. Examples of outreach activities may include, but are not limited to, advertising, personal contacts, newsletters, interviews, questionnaires, customer satisfaction surveys, and promoting awareness of GIPSA policies and procedures.

Term	Definition
Preventive Action	This term is used to define the correction of a potential non-conformance or a potential non-compliance. It documents the steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that haven't yet occurred. In general, the preventive action process can be thought of as a risk analysis process with a documented procedure.
Process	In general, a process uses resources to transform inputs into outputs using a set of interrelated or interacting activities; a series of steps leading to a desired result; a set or series of conditions, operations, or steps working together to produce a desired result. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out. This includes any process that falls within the scope of the QMS ranging from billing to inspecting to interacting with GIPSA.
Product	An output that results from a process. A product is normally thought to have physical, tangible properties but can be also be intangible, a thing or an idea, hardware or software, information or knowledge, a process or procedure, a service or a function, a concept or creation. An example of a tangible GIPSA product would be a certificate. An intangible product would be the delivery of the service; i.e., the timeliness and accuracy.
Purchased Product or Service	A product or service that is purchased through a supplier. A service may have intangible properties. Examples include software for generating certificates, contract samplers, or bags for holding samples.
Quality Coordinator	The individual within the OSP responsible for implementing and maintaining the QMS. This responsibility cannot rest with the top manager since this individual must report to the top manager.
Quality Management System (QMS)	A system of business practices that includes management responsibility, resource management, service delivery, and measurement, analysis, and improvement to direct and control an OSP with regard to quality.
QMS Manual or Quality Manual	A document that demonstrates the ability of the OSP to meet the requirements of the Quality Management Standards. It follows the sequence of the Standards and also includes the documented procedures and specific requirements in the Addendum. It can be a paper manual or an electronic manual.
QMS Review	A review to evaluate the overall performance of an organization's QMS and to identify improvement opportunities. These reviews are a formal documented activity carried out by the OSP top management and are done on a regular basis. This process is referred to as a Management Review.
Quality Objectives	Something sought, or aimed for, related to quality; goals, targets, or aims concerning product, service, processes, or systems related to quality. Quality Objectives must be measurable and achievable. They will change over time. In some cases a baseline must be established prior to setting an objective for improvement.

Term	Definition
Record	A historical artifact that contains objective evidence showing conformance to the Quality Management System. Records are always documents what has happened in the past; typically a record is considered “dead” since it cannot be changed. For example, a form that is completed is a record.
Resources	Includes personnel, finances, information and techniques (such as SOPs, handbooks, etc.), knowledge, skill, energy, and infrastructure (facilities, machines, tools, equipment, and technologies.
Root Cause	The source of defects, problems, or conditions. When performing corrective actions, the root cause must be discovered to prevent the problem from occurring again.
Standard Operating Procedures (SOP) or Work Instruction	A document that provides detailed information to control and carry out an activity in a step-by-step manner, including the associated inputs and outputs. Such a procedure defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work. This includes those procedures developed by the OSP and those published by GIPSA.
Service	A customer-oriented result that includes all work provided on behalf of GIPSA. The result is produced when the OSP performs activities that are oriented towards meeting customer needs and expectations. Examples include sampling, inspection, and weighing of commodities under the USGSA and AMA.
Service Delivery	Customer-oriented activities that are carried out by an organization to meet customer needs and expectations. A primary example is the official service performed by an OSP when it applies the Official Standards for Grain and standard testing methodologies in an impartial manner to accurately and consistently measure grain quality.
Standard	A standard is a written document. It is a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.
Supplier	An organization or person that provides a product or service to customers. Customers can be either internal or external to the supplier organization. External suppliers include retailers, distributors, manufacturers, utility companies, and services.
Top Management	A person or group of people with decision-making authority, whether it is the Owner, Chief Executive Officer (CEO), or Board of Directors. This authority includes making decisions that direct and control OSP operations at the highest level.
Validation	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. For example, retesting a sample and getting the same result is validation that the original test was done correctly.
Verification	Confirmation that the requirements stated in standards, work instructions, SOPs, or specifications have been met. For example, observing that an SOP is followed correctly is verification that the activity has been completed as planned.

Quality Standards

ELEMENT 1: GENERAL LEGAL RESPONSIBILITIES

All activities performed on behalf of GIPSA must comply with the United States Grain Standards Act (7 U.S.C. 71 et seq.), regulations (7 CFR Part 800, 801, 802, 810) and the Agricultural Marking Act of 1946 as amended (7 CFR Part 868), instructions, methods, and policy and procedures, as applicable. Major requirements are listed below or they are included in the Quality Standard; however, this list is not inclusive. A complete copy of all requirements should be obtained for reference.

All Official Service Providers must:

- a) Provide all products or services in the organization's assigned area, including official inspection services, as required by agreement, regulation, instruction and handbooks.
- b) Charge fees without discrimination and in accordance with a GIPSA approved fee schedule and maintain records of all fees and billing.
- c) Report to the responsible GIPSA contact person or office, information which shows or may show a violation of any provision of the USGSA, regulations, or instructions and information on any instructions which have been issued to agency personnel by GIPSA personnel or by any other person which are inconsistent with the USGSA, regulations or instructions.
- d) Provide sufficient security to ensure that official samples, records, equipment, forms or GIPSA owned property are reasonably secure from theft, alteration, or misuse.
- e) Respond to non-compliances and non-conformances in a timely manner.
- f) Comply with all applicable Federal, State or local regulations such as those for safety and sanitation.
- g) Notify the appropriate GIPSA contact person or office of any changes that may affect the quality of the product or service being provided on behalf of GIPSA prior to the change being made.
- h) Allow access to any structure, work area, records and documents that are used while manufacturing a product or performing services on behalf of GIPSA.

Operations performing Grain Inspection and Weighing Services also must:

- i) Rotate Personnel, where feasible, among elevators and other facilities as is necessary to preserve the integrity of the official inspection and weighing system.
- j) Ensure that no officer, director, stockholder, employee, or other related entity has a conflict of interest related to commercial grain merchandizing, transporting, storage or other related activity.
- k) Not perform unofficially services included as official services in their designation.
- l) Maintain a certificate control system for all official certificates it receives, issues, voids, or otherwise renders useless.
- m) Use only personnel licensed by GIPSA for performing official services.

Contractors or cooperators performing service for GIPSA must meet following quality standard requirements (Elements 2 – 9) in addition to all legal conditions stated in the contract or in the agreement.

ELEMENT 2: GENERAL QUALITY STANDARD REQUIREMENTS

An OSP must develop, document, implement, and maintain a QMS and continually improve its effectiveness while meeting the requirements set forth in this Management Standard.

OSP must accomplish the following:

- a) Identify and document QMS processes and their application throughout the organization in a QMS manual,
- b) Determine the criteria and methods required to ensure operational effectiveness and control of these QMS processes,
- c) Ensure the availability of resources necessary to support the operation, monitoring, measuring, and analyses of these QMS processes,
- d) Supply products and deliver services that meet customer needs in compliance with GIPSA requirements, and
- e) Implement necessary actions to achieve planned goals while continually improving the QMS processes.

These QMS processes must be managed by the OSP in accordance with the requirements of this Management Standard.

ELEMENT 3: DOCUMENTATION REQUIREMENTS

When establishing a QMS, an organization must document its quality system including everything it must do in support of a QMS prior to assigning responsibilities, resources, and processes. The type and extent of the documentation will depend on the size and complexity of the OSPs business operations as well as the nature of its products, services, and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.

3.1 QMS MANUAL

The OSP must prepare and maintain a quality manual to include the following:

- a) General information about the OSP,
- b) Scope of the QMS with a description of the specific services being provided on behalf of GIPSA, and
- c) All elements required by the QMS Management Standard including all documented procedures and records (*Reference Appendix A: Quick Reference for a consolidated listing*).

3.2 CONTROL OF DOCUMENTS

The OSP must provide a *documented procedure* that defines how they perform the following:

- a) Approve documents for adequacy prior to issue,
- b) Review, update as necessary, and re-approve documents,
- c) Ensure the changes and current revision status of documents are identified,
- d) Ensure the relevant versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable, and
- f) Prevent the unintended use of obsolete documents, and apply suitable identification when they are retained for any purpose.

The OSP must maintain a list of all documents identifying the current versions and whether the document is of internal or external origin.

3.3 CONTROL OF RECORDS

The OSP must provide a *documented procedure* that defines how they perform the following:

- a) Establish and maintain records to provide evidence of conformity to QMS requirements,

- b) Establish controls needed for the identification, storage, protection, retention, disposition of all records,
- c) Ensure all records are legible, readily identifiable, and retrievable, and
- d) Establish, maintain, and monitor a system for providing certificates, if applicable.

Management Responsibility

ELEMENT 4: MANAGEMENT COMMITMENT

Management establishes unity of purpose and direction of the organization by creating and defining the organization's policies and objectives and by ensuring that they are communicated to the entire organization.

4.1 QUALITY OBJECTIVES

The OSP top management must ensure that quality objectives are defined and managed for relevant functions and levels within the organization. The quality objectives must be measurable.

4.2 QMS PLANNING

The OSP top management must ensure the following:

- a) The planning of the QMS is carried out in order to meet the General Quality Standard Requirements stated in ELEMENT 2, as well as the quality objectives, and
- b) The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

4.3 RESPONSIBILITY AND AUTHORITY

The OSP top management must ensure that responsibilities and authorities are defined and communicated within the organization. For example, these responsibilities and authorities must be defined in job descriptions, the QMS manual, and an organizational chart.

4.4 QUALITY COORDINATOR

The OSP top management must appoint a Quality Coordinator, who, irrespective of other responsibilities, has the responsibility and authority to do the following:

- a) Ensure that processes needed for the QMS are established, implemented, and maintained,

- b) Report to top management on the performance of the QMS and any need for improvement, and
- c) Ensure the promotion of awareness of customer requirements throughout the organization (e.g., by communicating customer expectations and seeking ideas for improvement).

4.5 INTERNAL COMMUNICATION

The OSP top management must ensure that appropriate communication processes are established within the organization. Communication takes place regarding the effectiveness of the QMS, for example, through regular staff meetings, email notifications, or newsletters. Mechanisms for employees at *all levels* within the organization to communicate must be established.

4.6 QMS REVIEW

The OSP top management must review the organization's QMS, at regularly planned intervals (at least annually), to ensure its continuing suitability, adequacy, and effectiveness. The QMS review must assess opportunities for improvement and the need for changes to the QMS, including the quality objectives.

Records, such as an agenda and minutes, from QMS reviews must be maintained (*Reference 3.3 – Control of Records*).

4.6.1 REVIEW INPUT

Inputs to QMS reviews must at least include the information on the following:

- a) Results of internal and external audits,
- b) Customer feedback, such as surveys and complaints,
- c) Process performance and service delivery issues including status of quality objectives,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous QMS reviews,
- f) Changes that could affect the QMS or other areas such as organizational changes, new projects or processes, external changes, new regulations, or new technologies, and
- g) Recommendations for improvement.

4.6.2 REVIEW OUTPUT

Outputs from QMS reviews must include any decisions and actions related to the following:

- a) Improvement of the effectiveness (results) of the QMS and its processes,

- b) Service delivery improvements related to customer requirements, and
- c) Resource needs.

Responsibilities for actions must be noted with due dates.

ELEMENT 5: CUSTOMER FOCUS

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements, and should strive to exceed customer expectations.

5.1 CUSTOMER REQUIREMENTS

The OSP must ensure customer requirements are determined and are met with the aim of enhancing customer satisfaction. The OSP must determine requirements specified by the customer, including the following:

- a) The requirements for service delivery and post-delivery activities,
- b) Statutory and regulatory requirements related to official services, and
- c) Any additional requirements determined by the OSP.

5.2 CUSTOMER SATISFACTION

The OSP must provide a *documented procedure* and maintain records (*Reference 3.3 – Control of Records*) to assess customer satisfaction that defines and describes how they perform the following:

- a) Current outreach methods,
- b) Address customer complaints and/or disputes, and
- c) Use of information to make continuous improvements.

The OSP must determine and implement effective arrangements for communicating with customers in relation to service delivery, inquiries, contracts or service requests, including amendments and customer feedback.

5.3 CUSTOMER PROPERTY

The OSP must exercise care with property (including intellectual property such as confidential information) belonging to a customer while it is under the OSP control or being used by the OSP. The OSP must identify, verify, protect, and safeguard customer property provided for use or incorporation into the service delivery. If any customer property is lost, damaged, or found to be otherwise unsuitable for use, this must be reported to the customer and records maintained

(Reference 3.3 – Control of Records). Customer owned property must be in good working order when used to perform any work on behalf of FGIS.

Resource Management

ELEMENT 6: RESOURCES

An OSP cannot operate without adequate resources including personnel, buildings, equipment, and environment.

6.1 PERSONNEL

People at all levels who are fully involved in an organizations quality system are the essence of an organization. Their full involvement enables their abilities to be used for the organization's benefit. All OSP personnel performing work affecting quality must be competent on the basis of appropriate training, skills, and experience. The OSP must have a *documented procedure to*:

- a) Determine the necessary competence for all personnel performing work affecting service delivery,
- b) Provide training or take action to ensure competency needs are met,
- c) Evaluate the effectiveness of training or other actions taken,
- d) Ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives,
- e) Ensure personnel conflicts of interest are monitored and addressed, and
- f) Monitor the performance of its employees.

Records of supervision, training, skills, and experience must be maintained (*Reference 3.3 – Control of Records*).

6.2 INFRASTRUCTURE

The OSP must determine, provide, and maintain the infrastructure needed to achieve conformity to service delivery requirements in accordance with GIPSA requirements. Infrastructure includes:

- a) Facilities such as buildings, workspace, and associated utilities,
- b) The availability, maintenance, and use of GIPSA approved or allowed equipment such as measuring devices, machines, and tools, and

- c) Supporting services as applicable such as transportation or communication technology.

6.2.1 CONTROL OF EQUIPMENT

The OSP must establish processes to ensure the use of GIPSA approved or allowed equipment is controlled in a manner that is consistent with GIPSA requirements. To ensure equipment produces valid results, the OSP must:

- a) Identify equipment to enable the calibration status to be determined,
- b) Calibrate or verify equipment at specified intervals or prior to use, against measurement standards traceable to GIPSA measurement standards,
- c) Adjust or re-adjust equipment as necessary,
- d) Safeguard equipment from adjustments that would invalidate results, and
- e) Protect equipment from damage and deterioration during handling, maintenance, and storage.

Records of the results of calibration and verification (i.e. checktesting) must be maintained (*Reference 3.3 – Control of Records*).

6.2.2 WORK ENVIRONMENT

The OSP must determine and manage the infrastructure and work environment needed to achieve conformity to service delivery requirements in accordance with GIPSA requirements.

6.3 PURCHASE VERIFICATION

An OSP must ensure that any purchased products and services used to provide official services conform to specified requirements.

Purchase verification must include the following:

- a) A procedure for the development of purchase requirements prior to communicating with the supplier,
- b) The requirements for approval of product, procedures, processes and equipment as well as qualification of personnel,
- c) Criteria for supplier selection, evaluation, and re-evaluation,
- d) Evaluation and selection of suppliers based upon their ability to supply products or services to meet the OSP requirements, and
- e) The inspection or other activities necessary to ensure that any products or services purchased from a third-party supplier meet QMS or GIPSA requirements.

The type and extent of control applied to the supplier and the purchased product or service must be dependent upon the effect of the purchased product on the final product or service delivery.

Records of the results of evaluations and any necessary actions arising from the evaluation must be maintained (*Reference 3.3 – Control of Records*).

Service Delivery

ELEMENT 7: SERVICE DELIVERY PROCESSES

A consistent product or service that meets customer requirements is achieved more efficiently when activities and related resources are managed as a process.

7.1 SERVICE DELIVERY

The OSP must plan and carry out production and service delivery under controlled conditions. Controlled conditions include, as applicable, the following:

- a) The availability of information such as handbooks, directives, and other GIPSA publications that describe the scope of services (i.e. grain inspection),
- b) A sufficient number of qualified personnel,
- c) The availability of SOPs,
- d) The availability, maintenance, and use of GIPSA approved or allowed equipment,
- e) The implementation of monitoring and measurement to support QMS processes,
- f) The implementation of release, service delivery, and post-delivery activities, and
- g) A system to maintain integrity and traceability for all official services.

7.2 QUALITY ASSURANCE /QUALITY CONTROL PLAN

An OSP providing grain inspection service must establish and maintain the grading ability and performance of its inspectors through a structured and documented internal QA/QC plan including:

- a) Monitoring and evaluation interpretive results;
- b) Monitoring and evaluating equipment and testing results;
- c) Utilizing a defined sample selection method including either;

- i) Random sample selection or
- ii) Targeted by inspector, grain, damage, or condition;
- d) Taking corrective action when trends, biases and inspection differences are indicated by the monitoring data;
- e) Submitting to GIPSA of all required data within the required timeframe; and
- f) Attending training sessions when required by GIPSA.

Records must be kept of QA/QC alignment activities.

7.3 PRODUCTS OR SERVICES

The OSP must monitor and measure the characteristics of the product or service to verify that requirements have been met. This must be carried out in accordance with applicable SOPs.

Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of the product or service.

Product release and service delivery must not proceed until all the requirements have been satisfactorily met, unless otherwise approved by a relevant authority, and where applicable, by the customer.

7.4 CONTROL OF NONCONFORMING PRODUCTS OR SERVICES

The OSP must have a *documented procedure* to ensure that products or services which do not conform to requirements are identified and controlled to prevent unintended use or delivery. The OSP must address nonconforming products and services prior to delivery by taking action to correct the detected nonconformity. After release, the OSP must take appropriate action to issue a correct product.

Records of the nature of nonconformities and any subsequent actions taken must be maintained (*Reference 3.3 – Control of Records*).

Measurement, Analysis, and Improvement

ELEMENT 8: MONITORING AND MEASUREMENT

A factual approach to decision-making is based on the analysis of data and information.

8.1 INTERNAL AUDITS

The OSP must conduct internal audits at regularly planned intervals (at least annually) to determine if the QMS does the following:

- a) Conforms to the regulatory requirements for providing services on behalf of GIPSA,
- b) Conforms to the requirements of this Management Standard,
- c) Conforms to specific contractual requirements, if applicable,
- d) OSP established requirements as stated in its QMS Manual, documented procedures and work instructions, and
- e) Is effectively implemented and maintained.

An audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods must be clearly defined. Selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Internal auditors must meet OSP qualifications and must not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records must be defined in a *documented procedure*.

Records of internal audit results and follow-up actions must be maintained (*Reference 3.3 – Control of Records*).

8.2 PROCESSES

The OSP must apply suitable methods for monitoring and, where applicable, measurements of the QMS processes. These methods must demonstrate the ability of the processes to achieve planned results including analyzing characteristics and trends to identify opportunities for preventive action. When planned results are not achieved, corrective action must be taken.

ELEMENT 9: CONTINUAL IMPROVEMENT

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

The OSP must continually improve the effectiveness of the QMS through the use of the following:

- a) Quality objectives,
- b) Audit results,

- c) Analysis of data relating to customer satisfaction, conformity to products and services, and suppliers,
- d) QMS reviews, and
- e) Preventive and corrective actions.

9.1 PREVENTIVE ACTION

The OSP must determine action to eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions must be appropriate to the effects of the potential problems.

A documented procedure must be established to define requirements for:

- a) Determining potential nonconformance and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities (root cause),
- c) Determining and implementing action needed,
- d) Recording results of preventive action taken, and
- e) Reviewing preventive action taken to determine effectiveness.

Records of preventive actions must be maintained (*Reference 3.3 – Control of Records*).

9.2 CORRECTIVE ACTION

The OSP must take corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective action must be appropriate to the problem encountered.

A documented procedure must be established to define requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes for nonconformity (root cause),
- c) Evaluating the need for actions to ensure that nonconformities do not recur,
- d) Determining and implementing the corrective action needed,
- e) Recording results of corrective action taken, and
- f) Reviewing and assessing corrective action taken to determine effectiveness.

Records of corrective actions must be maintained (*Reference 3.3 – Control of Records*).

APPENDIX A: Quick Reference

This QMS Management Standard requires the following procedures to be documented and records to be maintained (other procedures and records must be maintained as required by GIPSA laws and regulations or as part of the OSP internal operations and business practices).

Documented Procedures	Records Maintained
3.2 Control of Documents	4.6 QMS Reviews
3.3 Control of Records	5.2 Customer Satisfaction
5.2 Customer Satisfaction	5.3 Customer Property
6.1 Personnel Management	6.1 Personnel
7.3 Control of Nonconforming Products or Services	6.2.1 Control of Equipment (Checktesting)
8.1 Internal Audits	6.3 Supplier Management (Evaluations)
9.1 Preventive Action	7.2 Product or Services (Release)
9.2 Corrective Action	7.3 Control of Nonconforming Products or Services (Nonconformities)
	8.1 Internal Audits
7.2 QA/QC Plan	9.1 Preventive Actions
	9.2 Corrective Actions

APPENDIX B: Publications

The following publications list is a compilation of handbooks and directives necessary for conducting “official services” on behalf of GIPSA. These publications provide the guidelines and regulations. The most recent electronic version of each of the FGIS Program Handbooks may be found at <http://151.121.3.117/reference-library/handbooks/handbooks.htm>.

Number	Date	Title	QMS Reference
P.L. 94-582	08-11-1916 <i>Amended 1976</i>	United States Grain Standards Act of 1976 (USGSA)	
7 CFR Part 800		Regulations under the USGSA	
	11-17-95 Issuance Change (IC) #88	Grain Inspection Handbook I – Grain Sampling	
	08-09-04 IC #97	Grain Inspection Handbook II – Grain Sampling Procedures	
	06-12-00 IC #96	Grain Inspection Handbook III – Inspection Procedures	
	04-15-97 IC #89	Grain Inspection Handbook IV – Forms and Certifications	
	03-28-05 IC #25	Weighing Handbook	
	04-18-05 IC #11	Aflatoxin Handbook	
	08-30-04 IC #3	DON (Vomitoxin) Handbook	
	10-04-96 IC #2	Equipment Handbook	
	10-28-93 IC #3	Fumigation Handbook	
	11-07-03 IC #2	Mechanical Sampling Systems Handbook	
DJ GAC 2100	01-08-99	Moisture Handbook	
	07-25-05 IC#5	NIRT Handbook	
	10-01-96	Quality Handbook	
FGIS 2220.1 (FGIS 421-1)	11-01-96	Billing Document Completion Procedures for Grain. Inspected by FGIS in the United States	
FGIS 9000.5	03-11-04	Remote Issuance of Official Certificates	
FGIS 9010.1	02-25-99	Resolving Customer Concerns	
FGIS 9020.1	05-01-97	Exemptions and Waivers of Official Inspection and Class X Weighing Requirements – Attachments 1 and 2	
FGIS 9060.2	05-01-97	Implementation of the FGIS-FDA Memorandum of Understanding – Attachments 1, 2, and 3	

Number	Date	Title	QMS Reference
FGIS 9060.3	06-11-04	Application and Agreement for Contract Service, Form FGIS-4	
FGIS 9070.2 (FGIS 907.2)	03-05-99	Management Control Programs	
FGIS 9070.3	10-5-00	Conflicts of Interest	
FGIS 9070.5	09-18-96	Grain Handling Practices	
FGIS 9070.6	10-05-00 06-21-01 12-20-02 09-01-04	Reporting Violations of the U.S. Grain Standards Act and the Agricultural Marketing Act of 1946 Issuance Change No. 1 for Attachment Issuance Change No. 2 for Attachment Issuance Change No. 3 for Attachment	
FGIS 9100.1 (FGIS 910.1)	10-08-98	Foreign Quality and Weight Complaints	
FGIS 9100.4	05-01-97	Certificate Accountability	
FGIS 9100.7	01-03-97	Fees for Official Agency Services	
FGIS 9120.1	05-01-97	The Collection and Use of Wheat Variety Type Samples	
FGIS 9160.1 (FGIS 916.1)	12-15-99	Closed-Circuit Television Installations	
FGIS 9160.3 (FGIS 916.3)	03-06-95	Parameters for Automated Monitoring and Supervision of Official Weighing	
FGIS 9160.4	12-15-97	Grain Handling System Testing	
FGIS 9170.3	01-30-97	Forwarding Samples to the Technical Services Division	
FGIS 9170.12	05-01-97	Furnishing Official Samples	
FGIS 9170.13	05-01-97	Uniform File Sample Retention System FM-PPB A,C	
FGIS 9180.14	08-04-03	Inspecting Export Grain for Weed and Crop Seeds	
FGIS 9180.15	04-02-99	Inspection of Export Lots for Cottonseed	
FGIS 9180.16	07-22-99	Inspection of Export Lots of Soybeans for Ragweed Seeds	
FGIS 9180.17	07-20-04	Inspection of Export Wheat Lots for Canada Thistle Seed	
FGIS 9180.18	04-21-03	Special Quality Factor Information for Wheat and Malting Barley Shipments to European Community	
FGIS 9180.34	03-24-05	Phytosanitary Inspection of Export Grain Shipped from Interior Locations	
FGIS 9180.35	05-01-97	Phytosanitary Inspection	
FGIS 9180.36	08-16-04	Warehouse Sample-Lot Inspections	
FGIS 9180.38	05-01-97	Falling Number Determination for Wheat	
FGIS 9180.40	08-08-05	Pesticide Residue Testing for Grain	
FGIS 9180.41	04-22-97	Sacked Grain	
FGIS 9180.47	06-15-99	Examination of Grain for the Presence of TCK Smut Spores	
FGIS 9180.48	03-14-05	Stowage Examination Services	
FGIS 9180.49	09-13-96	Grading and Certification of Grain Containing Diatomaceous Earth and Silica Gel	

Number	Date	Title	QMS Reference
FGIS 9180.54	5-01-97	Fees and Billing for Canola: Oil Content and Gas Chromatographic Determinations of Glucosinolates and Euricic Acid	
FGIS 9180.55	08-01-03	Official Commercial Inspection Services	
FGIS 9180.56	05-01-97	Testing Corn Gluten Feed for Starch, Fat, and Protein	
FGIS 9180.59	01-20-98	Combined Sample Analysis for Combined Land Carrier Inspections	
FGIS 9180.60	12-30-30	Inspection of Khorasan	
FGIS 9180.61	08-01-05	Official Calibrations for the Dickey-John GAC 2100 Moisture Meter	
FGIS 9180.63	09-17-01	Inspection of Hulless Oats	
FGIS 9180.65	09-25-01	Inspection of Hulless Barley	
FGIS 9180.66	08-18-03	Zearalenone Testing	
FGIS 9180.67	01-24-05	Transgenic Statements for Grain and Graded Commodities	
FGIS 9180.68	07-18-00	Cross Utilization of Equipment	
FGIS 9180.70	03-25-02	Inspection of Cracked Corn	
FGIS 9180.71	12-29-03	03 Fumonisin Testing Services	
FGIS 9180.74	06-11-04	Service Fees and Billing Codes	
FGIS 9180.75	10-15-03	Testing for Presence of Waxy Corn	
FGIS 9180.77	12-29-03	Official Criteria Factor for Malting Barley	
FGIS 9180.78	12-06-04	Procedures For Bulk Grain Exported In Containers	
FGIS 9181.1	03-25-02	Testing for Star Link Corn-Lateral Flow Test Strip Method	
FGIS 9230.1	09-04-00	Licensing Program	
FGIS 9290.16	07-30-99	Improving Service Delivery and Enhancing Information Sharing between the Official Agencies and the Official FGIS System	